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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,422	06/02/2005	Serge Tretjak	FR-AM 1905	3179
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OH, TAYLOR V				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/537,422

Applicant(s)

TRETJAK ET AL.

Examiner

Taylor Victor Oh

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Final Rejection

The Status of Claims

Claims 1-9 are pending.

Claims 1-9 are rejected.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of Claims 1-7 under 35 U.S.C. 112, first paragraph, has been maintained due to applicants' failure to modify the claims in the amendment.

Claim Rejections-35 USC 103

1. Applicants' argument filed 1/15/08 have been fully considered but they are not persuasive.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The rejection of Claims 1-9 under 35 U.S.C. 103(a) as being unpatentable over Weisberg et al (US 2,406,648).

The rejection of Claims 1-9 under 35 U.S.C. 103(a) as being unpatentable over Weisberg et al (US 2,406,648) has been maintained for the reasons of the record on 10/30/07.

Applicants' Argument

2. Applicants argue the following issues:
 - a. The specification provides several examples of suitable esterification catalysts ; a skilled artisan in the art would be familiar with esterification reactions in general and would be able to select a suitable catalyst without undue experimentation based on the direction as to several suitable catalyst give in the specification; Therefore, the specification provides enablement for the claims therefore, the rejection should be withdrawn.
 - b. The prior art encounters the formation of unavoidable sludge unlike the present invention which uses the lactic acid as the starting material to

avoid its formation of the sludge. Therefore, it is unobvious over the prior art.

First, regarding the first applicant's argument, the Examiner has noted applicants' argument. However, Claims 1-7 are still rejected under 35 U.S.C. 112, first paragraph, because the specification while being enabling for H_2SO_4 , H_3PO_4 , methanesulfonic acid or Amberlyst 15 as a catalyst, does not reasonably provide enablement for any catalysts generally. The claim(s) contains subject matter, for example all kinds of catalyst, which were not described in the specification in such a way as to enable one skilled in the art of chemistry to use the invention.

Furthermore, the instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation, citing *Ex Parte Forman*, 230 USPQ 546 (BdApl 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence or absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,

Art Unit: 1625

- 6) the relative skill of those in the art,
- 7) the predictability of the art, and
- 8) the breath of the claims.

The states of the prior art are described as followed:

Gabriel et al (U.S. Pat. No. 1,668,806) who prepared 1-butyl lactate by dehydrating 70% lactic acid with excess 1-butanol at 117° C., followed by addition of HCl catalyst, followed by refluxing and esterification with addition of excess 1-butanol and drawing a 1-butanol water azeotrope overhead. The process involved dehydration of the system and removal of water prior to the esterification step.

Bannister (U.S. Pat. No. 2,029,694) describes a method for producing esters that have boiling points of at least 120° C. The lactic acid and acidic catalyst are charged to a reactor

and heated to the boiling point of the ester or not less than 20° C. below this temperature. The alcohol is introduced into the reactor below the surface of the hot partially dehydrated acid. The ester, water of reaction, and excess alcohol are taken off overhead. For example, methyl lactate is formed at temperatures from 130 to 140° C. by introducing methanol into partially dehydrated lactic acid. The overhead distillate is 8–10% water, 42–42% methanol, and 50% methyl lactate, by weight. For every 4.8 moles of methyl lactate produced in the system a total of 17.9 moles of methanol is fed to the system. Most or all of the water taken overhead (5.0 moles) is produced by the esterification reaction. The effective feed water level is 0.2 moles. This means that the feed streams are essentially water free.

Weisberg et al (US 2,406,648) discloses the following summary process:

In general, a method in accordance with the present invention includes esterifying an alkali metal or alkaline earth metal lactate with a lower alkyl alcohol, the lactate ester of which is water-soluble such as, for example, methyl, ethyl, or isopropyl alcohol, in the presence of a strong mineral acid. During the formation of the ester, the action of the acid on the lactate salt unavoidably causes the formation of an alkali or alkaline earth metal salt, which with impurities in the lactate salt raw material forms a sludge which has the tendency to occlude and retain tenaciously a portion of the ester. The method of the present invention includes flash distillation of the ester, any excess alcohol and the water present or formed during esterification under conditions such that a clean separation of the liquid from the sludge is obtained. The liquid components may then be distilled to separate the alcohol from the aqueous solution of the ester and the water is then distilled off azeotropically to produce a substantially pure anhydrous ester.

As the prior art have been discussed in the above, there is no conclusive data that all kinds of catalysts would be required to produce the final desired product except some acidic esterification catalyst, such as, a strong mineral acid.

In the instant case, the instant claimed invention is highly unpredictable since one skilled in the art would recognize that any catalyst would not work on the claimed process in the same way as the catalyst such as H_2SO_4 , H_3PO_4 , methanesulfonic acid or Amberlyst 15 disclosed in the specification. For example, Gardener (US 3,878,261) discloses the super acid catalyst of SbF_5 and $\text{CF}_3\text{SO}_3\text{H}$ used for isomerizing paraffins containing 4 to 12 carbons in a feed stream (see abstract page); furthermore, according to the text book, March's Advanced Organic Chemistry (March et al., 4th ed. 1992), it describes that another super acid, $\text{FSO}_3\text{H-SbF}_6$, is used in the formation of

Art Unit: 1625

a carbocation, such as tert-butyl cation (see p. 219, the fourth paragraph) from isobutane unlike the claimed process.

Furthermore, the specification of the claimed invention does support the very idea of the unpredictable aspect of the catalysts by disclosing the specific and workable catalyst for the esterification in the above, not all kinds of the catalyst known in the art.

Moreover, chemical reactions are well-known to be unpredictable, *In re Marzocchi*, 169 USPQ 367, *In re Fisher*, 166 USPQ 18. Additionally, catalytic processes, such as are present here, are inherently unpredictable. The U.S. District Court District of Connecticut held in *MOBIL OIL CORPORATION v. W.R. GRACE & COMPANY*, 180 USPQ 418 that "there is an inherent mystery surrounding the unpredictability of the performance of catalysts; a mystery which is generally recognized and acknowledged by chemists in the cracking art. This is one more reason why the presumption of patent validity "should not be disregarded especially in a case of this sort where the intricate questions of [bio]chemistry involved are peculiarly within the particular competence of the experts of the Patent Office." *Merck & Co. v. Olin Mathieson Chemical Corp.*, 253 F.2d 156, 164, 116 USPQ 484, 490 (4th Cir. 1958)". "The catalytic action can not be forecast by its chemical composition, for such action is not understood and is not known except by actual test, *Corona Cord Tire Co. v. Dovan Chemical Corp.*, 276 U.S. 358, 368-369 (1928). Also see, *Application of Grant*, 304 F.2d 676, 679, 134 USPQ 248, 250-251 (CCPA 1962); *Rich Products Corp. v. Mitchell Foods, Inc.*, 357 F.2d 176, 181, 148 USPQ 522, 525-526 (2d Cir. 1966), cert. denied

Art Unit: 1625

385 U.S. 821, 151 USPQ 757 (1966); *Ling-Temco-Vought, Inc. v. Kollsman Instrument Corp.*, 372 F.2d 263, 268, 152 USPQ 446, 450-451 (2d Cir. 1967); *Georgia-Pacific Corp. v. United States Plywood Corp.*, 258 F.2d 124, 132-133, 118 USPQ 122, 128-129."

Therefore, from the above, it is clear that the use of a generic phrase "a catalyst" can not ensure to form the desired claimed product in a good yield.

The direction present in the instant specification is that not any catalyst can be led to the formation of the desired product. According to the specification, it is silent as to how any acidic catalyst can be led to the formation of the desired product and fails to provide guidance as to whether any acidic catalyst is sufficient enough to allow to form the desired product in sufficient quantities; the specification fails to provide a correlation between the claimed process of the invention and the functional language of any acidic catalyst .

In the instant case, the claim encompasses all the various catalysts. Applicants' specification provide only one particular exemplified catalyst compounds ,such as sulfuric acid as shown in the specification (see page 8). However, this can not be the representatives for all the catalysts which would work for the claimed process. Thus, the specification fails to provide working examples as to how other types of catalysts can be resulted in the claimed products, i.e. again, there is no correlation between the functional language of any catalyst and the desired final product.

The breadth of the claims is that any acidic catalyst would work on the claimed process in the same way as those disclosed catalyst in the specification without

Art Unit: 1625

considering the affect or impact of the different types of catalysts on the starting compounds; for example, the super acid $\text{FSO}_3\text{H-SbF}_6$ disclosed in March's Advanced Organic Chemistry (March et al , 4th ed. 1992) has a high likelihood of removing hydrogen ions from the reactants, instead of helping them to form the desired product , thereby detrimentally affecting the yield of the desired final product.

The quantity of experimentation needed is large. One of skill in the art would need to determine which one of the catalysts would be capable of forming the desired product and would furthermore then have to determine which one of the catalysts would not be resulted in the claimed desired compounds in a sufficient quantity.

Even though the level of skill in the esterification is high, the skilled artisan employing this process would be a BS chemist working in the a laboratory facility. He would know how to use the taught catalyst, but not how to select other catalyst without trail and error.

Therefore, in view of the Wands factors and In re Fisher (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test which acidic catalyst can be employed to produce the desired claimed compound encompassed in the instant claims, with no assurance of success.

Therefore, applicants' arguments are not persuasive.

Second, regarding the second argument, the Examiner has noted applicants' argument. However, the claims are not directed to avoiding the formation of the

Art Unit: 1625

sludge by using the lactic acid as the starting material, but they are directed to a continuous process for the preparation of ethyl acetate by esterifying lactic acid with ethanol. Unlike applicants' argument, Weisberg et al expressly the process of water-soluble alkyl lactates by reacting lactate salt, alcohol, and acid catalyst using the flash separator in conjunction with the fractionating distillation column; furthermore, the same prior art does offer guidance that water-insoluble alkyl lactates can have a good use for lacquer solvents and other purposes (see col. 1, lines 5-11). Therefore, it would have been obvious to the skilled artisan in the art to be motivated to change from the salt of the lactic acid starting material to the regular lactic acid depending on the final end use of the desired product. This is because the skilled artisan in the art would expect or predict such a modification to be feasible and successful as guidance shown in the prior art. Therefore, the prior art is still relevant to the claimed invention.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 1625

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Taylor Victor Oh/
Primary Examiner, Art Unit 1625
4/27/08
Taylor Victor Oh, MSD,LAC
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Art Unit : 1625
